



Legal Division

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By Federal Express

December 18, 1995

William C. Lucas, Esq. Zeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19897

TAP and Zeneca Marketing Activities RE:

Dear Mr. Lucas:

This letter is in response to your correspondence of October 13, 1995.

GENERAL COMMENTS

Generally speaking, we believe your correspondence adequately explains some, but not all, of the improper Zeneca sales and marketing activities described in my letter of September 26, 1995. As to your allegations against TAP, our investigation of TAP's allegedly improper marketing activities leads us to conclude that the activities you identified were not in any way illegal or improper. In fact, in some of the instances cited Zeneca has either ignored or overlooked lawful explanations suggested on the face of the documents enclosed with your letter.

Specific responses to the matters asserted in your letter are set forth below.

COMMENTS ON ZENECA RESPONSES TO TAP ALLEGATIONS

TAP Allegation No. 1

We have no way of knowing whether the fifty sample depots of Zoladex provided to Drs. River and Oyer were "appropriately marked and labelled" and whether "it was understood by the practice that the samples were not subject to reimbursement by Medicare." In the absence of any direct evidence to the contrary, we will accept your explanation, though we still have concerns about the language in the Zeneca sales promotion aid referring to the fifty free depots being "AN ADDED INCENTIVE ... FOR THE INITIAL CONVERSION TO ZOLADEX."

6(e)and protective orders in U.S. v. Makenzie 01-CR-01350-DPW (D.MASS) and in re Lupron Marketing and Sales Pratices Litigation



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As to your counter-allegation concerning TAP's alleged proposal to Dr. Berkman (your Exhibit A), we do not believe this proposal was improper in any way. It is clear from the document itself that the free goods offered were for trial purposes only and were not considered in the financial analysis. The last sentence on the second page of the proposal specifically states: "The free drug is not considered in reimbursement amounts since we stress the importance of not billing for the free drug given to your office."

TAP Allegation No. 2

Our original investigation disclosed numerous instances of Zeneca sales representatives misrepresenting TAP pricing, of which Michele Willingham's letter was but one example. Therefore, we think you are missing the point to focus on Michele Willingham's letter as an isolated incident involving a minor deviation. We are concerned about the apparent pattern of such activities and can provide other examples of such conduct if necessary.

My understanding is that TAP's volume pricing discount schedule is publicly available, so it would not have been necessary for Zeneca to contact TAP to verify TAP's pricing information. Of course we recognize that competitors contacting each other for pricing information is improper and we would never expect Zeneca to do this, nor would TAP do so itself.

TAP Allegation No. 3

We accept your explanation as to the purchasing groups involved banding together to enable them to take advantage of volume pricing discounts. However, we must take issue with the self-righteous tone of your response.

Contrary to the statements in your letter, TAP did not have any definite information concerning the existence of the purchasing group, the identity of group members and the group's participation rules and eligibility. TAP's proposal (your Exhibit B) assumed hypothetically that the practice group would band together to take advantage of volume discounts. Further, because of the same concerns you pointed out in your letter about TAP Allegation No. 2, obviously TAP could not call Zeneca directly to obtain information about Zeneca customers.

TAP Allegation No. 4

It may well be that Zeneca sales representatives believed in good faith that their statements concerning anticipated new product offerings satisfied FDA regulatory

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requirements. However, as I am sure you are aware, it is important to distinguish between stating that products <u>might</u> be available pending regulatory approvals and making an unqualified statement that certain <u>products will</u> be available on specified dates, and the proposal in question does indicate that Zeneca "will launch" these products within specified time frames.

At to your counter-allegation concerning TAP's conduct at a recent American Urologic Association meeting in Las Vegas, we believe this counter-allegation is without any merit and that the situations compared are not at all similar. TAP representatives merely stated at the Las Vegas meeting that TAP was conducting research on a four month Lupron depot formulation. Unlike Zeneca representatives in the example referenced above, TAP representatives never stated that such a product definitely would be available within a specified time period.

TAP RESPONSES TO ZENECA ALLEGATIONS

Zeneca Allegation No. 1

The letter from TAP's Bill Soucie to Dr. John Williams (your Exhibit C) does contain some inartfully worded statements which, though they were made with proper and lawful intentions, may be misconstrued when taken out of context. Mr. Soucie was reprimanded by his manager within days of sending out this letter and counseled to more carefully explain the TAP programs involved in future communications.

The TAP representative was referring to two TAP charitable programs -- Patient First and TAP Care (see copies of enclosed program materials). The message he intended to convey, which we admit should have been explained more clearly, was that patients who met the eligibility criteria for either of these two indigent programs could receive free drug and that if invoices had already been sent by TAP for these patients, those invoices would be amended as appropriate.

As to your unfair competition allegations, we do not believe any of the statements contained in Mr. Soucie's letter constitute acts of unfair competition.

Zeneca Allegation No. 2

Your letter seems to suggest that the page entitled "Prices" (part of your Exhibit D) is referring to Lupron versus Zoladex, but neither product is mentioned on this page. Further, we do not find in this document any inappropriate comparative claims about Zoladex.

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Zeneca Allegation No. 3

TAP has no way of knowing the source of the document comparing Lupron to Zoladex (part of your Exhibit E), but, even if it did originate with TAP, we do not see any false or misleading statements in the document. Further, we note that this document dates back to 1993, leading us to question its relevance as evidence of any current activities. By contrast, all of the Zeneca activities TAP has questioned occurred this year.

Zeneca Allegation No. 4

The TAP price quotes you reference (your Exhibit F) were all proper and lawful at the time they were given for the states in which they were given. Prices may vary slightly from state to state because of state sales taxes.

Zeneca Allegation No. 5 -

We do not believe the document you reference (your Exhibit G) is misleading. As to the first point, the enclosed Zoladex package insert mentions 28 day dosing nine times. As to the second point, it is not unreasonable to conclude that a room is required for the administration of the implant product in question. Finally, as to the third point, Zeneca's package insert does suggest that a local anesthetic be used (see highlighted language in attached copy).

CONCLUSION

Unless you wish to discuss any of these matters further, we will consider these matters closed. We expect Zeneca to monitor its sales representatives to ensure that they do not engage in illegal or improper activities and, if we discover any future instances of illegal or improper activities, we will bring them to your attention. TAP will continue to do likewise with its sales representatives, as TAP has always done.

Very truly yours,

Mark J. Thebuluger

Counsel

Encl.

cc: Yasu Hasegawa (all by fax, w/o encl.)

Dean Sundberg Jim Salanty

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bcc: Brian Smith (w/o encl.)

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